

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0391]

DDM

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Certifier A. Corbin

Draft Guidances for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Dental Noble Metal Alloys and Class II Special Controls Guidance Document: Dental Base Metal Alloys; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance documents entitled “Class II Special Controls Guidance Document: Dental Noble Metal Alloys” and “Class II Special Controls Guidance Document: Dental Base Metal Alloys.” These draft guidance documents describe means by which noble metal alloy and base metal alloy devices may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to amend the identification and classification regulations of gold-based alloys and precious metal alloys for clinical use and base metal alloy devices presently classified in class II. FDA is also exempting these devices from premarket notification requirements.

DATES: Submit written or electronic comments on the draft guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5” diskette of the draft guidance documents entitled “Class II Special Controls Guidance

Document: Dental Noble Metal Alloys” and “Class II Special Controls Guidance Document: Dental Base Metal Alloys” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidances.

Submit written comments concerning these draft guidances to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Michael E. Adjodha, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, ext. 123, e-mail: mea@cdrh.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issued a final rule classifying gold-based alloys and precious metal alloys for clinical use and base metal alloy devices in the **Federal Register** of August 12, 1987 (52 FR 30082). These devices were classified before the provisions of the Safe Medical Devices Act of 1990 (SMDA) broadened the definition of class II devices to establish special controls beyond performance standards. FDA published a proposed rule in the **Federal Register** of December 1, 2003 (68 FR 67097) to amend the classification regulation of these class II devices. FDA received three comments.

FDA received one comment from a consumer and one (in duplicate) from a trade association. Both comments were in support of the proposed reclassification with minor modifications suggested. The consumer comment states that the name of the regulation “gold based alloys and precious metal alloys for clinical use” is unscientific because gold is, by definition, a precious metal. FDA agrees with this comment and has amended § 872.3060 (21 CFR 827.3060) to read “noble metal alloy” and deleted “for clinical use.”

The subject of the trade association comment was that the scope of the dental base metal alloys guidance is not clear as to what alloys are subject to the guidance. FDA agrees with this comment and has modified the scope of the guidance to define the devices not clearly addressed by the guidance.

The trade association comment also recommended that FDA’s recommendation that the labeling for nickel-containing alloys contain a contraindication for hypersensitive individuals is unnecessary because nickel has been demonstrated to be biocompatible. FDA disagrees that the labeling should not contain a contraindication for nickel hypersensitive individuals. FDA believes that this warning is needed to minimize the potential for adverse events associated with improper use of this device.

Following the effective date of the final rule exempting the device, manufacturers of these devices will need to address the issues covered in this special control guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness. If manufacturers cannot comply with these recommendations or equivalent measures, they will not be exempt from the requirements of premarket notification and will need

to submit a premarket notification and receive clearance for their device prior to marketing.

II. Significance of Guidance

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidances represent the agency's current thinking on base metal alloy and noble metal alloy devices. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act of 1995

These guidances contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA). The collections of information addressed in the guidance documents have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidances have been approved by OMB under the PRA under OMB control number 0910–0485.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments <http://www.fda.gov/dockets/ecomments> or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Copies of the draft guidance

documents and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

To receive “Class II Special Controls Guidance Document: Dental Noble Metal Alloys” by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the voice prompt, press 1 to order a document. Enter the document number 1415 followed by the pound sign (#). Follow the remaining voice prompts to complete your request. To receive “Class II Special Controls Guidance Document: Dental Base Metal Alloys” by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1416 followed by the pound sign (#). Follow the remaining voice prompts to complete your request. Persons interested in obtaining a copy of these draft guidances may also do so using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturer’s assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at

<http://www.fda.gov/cdrh>. A search capability for all CDRH documents is available at <http://www.fda.gov/cdrh/guidances.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

Dated: 8/11/04
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